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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/601,941	06/23/2003	Robert E. Sosnowski	1107-3 CIP	7846

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EXAMINER	
COTTON, ABIGAIL MANDA	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,941	SOSNOWSKI ET AL.	
	Examiner	Art Unit	
	Abigail M. Cotton	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *6/23/03, 10/8/03 and 11/23/04*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *30-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *30-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 30 and 31, drawn to a composition for reducing the risk or progression of Alzheimer's disease comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

II. Claims 31 and 33, drawn to a method of reducing the risk or progression of Alzheimer's disease by administering a composition comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

III. Claims 34 and 36, drawn to a composition for reducing the risk or progression of diabetic neuropathy, comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

IV. Claims 35 and 37, drawn to a method of reducing the risk or progression of diabetic neuropathy, comprising administering a composition comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

V. Claims 38 and 40, drawn to a composition for reducing the risk or progression of retinopathic disease comprising dextromorphan, folic acid

or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

VI. Claims 39 and 41, drawn to a method of reducing the risk or progression of retinopathic disease by administering a composition comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

VII. Claims 42 and 44, drawn to a composition for reducing or eliminating apoptosis or neuronal cell death comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

VIII. Claims 43 and 45, drawn to a method for reducing or eliminating apoptosis or neuronal cell death by administering a composition comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

IX. Claims 46, 48 and 50-51 drawn to a composition for treatment of elevated homocysteine comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

X. Claims 47, 49 and 52-53, drawn to method of treatment of elevated homocysteine by administering a composition comprising dextromorphan, folic acid or folate, vitamin B6 and vitamin B12, classified in class 514, subclasses 185, 249, 289, for example.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, V, VI, IX and II, IV, VI, VIII, X are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case, the risk or progression of Alzheimer's disease can be reduced by using a materially different product, such as donexepil, etc. Also the risk or progression of diabetic neuropathy can be reduced by using a materially different product, e.g. gabapentin or tramadol. The risk or progression of retinopathic disease can also be reduced using a materially different product, e.g. via laser treatment. The reduction of apoptosis or neuronal cell death can also be reduced using a materially different product, e.g. neuroprotective agents such as lithium. The treatment of elevated homocysteine levels can also be treated using a materially different product, e.g. prescription multivitamins.

Because these inventions are distinct for the reasons given above and the search required for Groups I, III, V, VII and IX is not required for Groups II, IV, VII, VIII and X, restriction for examination purposes as indicated is proper. It is noted that while the searches of the Groups may be overlapping, there is no reason to believe that the

searches would be co-extensive. In searching Groups I, III, V, VII and IX, the Examiner will be focusing on the patentability of the product itself, and not the process of using of Groups II, IV, VII, VIII and X. Conversely, in searching Groups II, IV, VII, VIII and X, the Examiner will be focusing on the patentability of the process and not the product itself. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions I, III, VI, VII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effect (MPEP 806.04, MPEP 808.01.) In the instant case the different inventions have different modes of operation, such as in the treatment of Alzheimer's vs. diabetic neuropathy, etc.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups I, III, VI, VII and IX may be overlapping, there is no reason to believe that the searches would be co-extensive. For example, in searching Group I, the Examiner will be focusing on the composition suitable for treatment of Alzheimer's and not the composition for treatment of diabetic neuropathy of Group III. Conversely, in searching Group III, the Examiner will be focusing on the patentability of composition for treating diabetic neuropathy, and not the composition for treatment of Alzheimer's as in Group I. Accordingly, a search for both groups would pose an undue burden on the Office.

Inventions II, IV, VI, VIII and X are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effect (MPEP 806.04, MPEP 808.01.) In the instant case the different inventions have different functions, such as in the treatment of Alzheimer's vs. diabetic neuropathy, etc.

Because these inventions are distinct for the reasons given above, restriction for examination purposes as indicated is proper. It is noted that while the searches of Groups II, IV, VI, VIII and X may be overlapping, there is no reason to believe that the searches would be co-extensive. For example, in searching Group II, the Examiner will be focusing on the method of treatment of Alzheimer's disease, and not the method of treatment of diabetic neuropathy of Group IV. Conversely, in searching Group IV, the Examiner will be focusing on the patentability of treating diabetic neuropathy according to the method, and not the method of treatment of Alzheimer's disease as in Group II. Accordingly, a search for all groups would pose an undue burden on the Office.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a

matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Due to the complicated nature of the restriction, the restriction requirement is being made via written correspondence in lieu of a telephone interview.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abigail M. Cotton whose telephone number is (571) 272-8779. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AMC

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER